

REMARKS

Status of the Claims

Claims 12, 14, 15, 17, 21, 22, 26, 30 and 31 are pending in this application. Claim 12 is independent. Claim 12 has been amended, which is supported by at least page 12, lines 7-12 of the specification. Thus, no new matter has been added.

The Examiner is respectfully requested to enter this Amendment After Final, in that it raises no new issues but merely places the claims in a form more clearly patentable over the references of record. In the alternative, the Examiner is respectfully requested to enter this Amendment After Final in that it reduces the issues for appeal.

Reconsideration of this application is respectfully requested.

Information Disclosure Citation

The Examiner has not provided Applicants with an initialed copy of the PTO-SB08 form filed with the Information Disclosure Statement filed on November 2, 2010. In particular, the Examiner has crossed out three Japanese references (JP 2002-531510; JP 2003-534777; and JP 11-507406), asserting that a legible copy of each cited foreign patent document has not been submitted. In response, Applicants provide a full copy of the above three Japanese References and English abstracts thereof, all of which are legible, together with this Reply.

Also, Applicants submitted an IDS on February 25, 2011.

Each of the Information Disclosure Statements filed by Applicants to date and initialed PTO-SB08 forms are requested by the Examiner in the next Office Action.

Issue under 35 U.S.C. § 103(a)

Claims 12, 14, 15, 17, 21, 22, 26, 30 and 31 stand rejected under 35 U.S.C. §103(a) as being obvious over Bijlsma in combination with De La Torre et al. (Riviste Italiana Di Nutrizione Parenterale Ed Enterale, Vol. 21, No. 3, pp 105-111, Wichig Editore, Milano, IT, January 1, 2003). This rejection is respectfully traversed.

The Present Invention

The present invention is directed to a method for ameliorating or treating an inflammatory bowel disease (IBD), comprising administering a composition comprising galactomannan in an amount sufficient to lower the activity of myeloperoxidase and TNF- α to a patient suffering from said IBD, wherein said galactomannan is a degraded galactomannan having an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5 (w/v)% aqueous solution of the degraded galactomannan, and produced by hydrolyzing guar gum with β -mannanase (claim 12) (emphasis added).

Distinctions Over the Cited Art

As recited in the claims, the present composition requires a specific degraded galactomannan which has an average molecular weight of from 8,000 to 50,000 and a viscosity of 10 mPa·s or less, as determined by 0.5(w/v)% aqueous solution of the degraded galactomannan, and produced by hydrolyzing guar gum with β -mannanase.

In contrast, Bijlsma discloses slightly negatively charged non-digestible polysaccharides. As shown in Example 1 of Bijlsma, hydrolyzed guar gum is subjected to further modification by addition of pyridine sulphur trioxide. In Bijlsma, such further chemical modification is carried out for more effectively reducing transport via the tight junctions of the intestines. As illustrated in Fig. 2 of Bijlsma, carboxydextran effectively inhibit permeability in comparison with neutral dextrans. As such, Bijlsma's polysaccharide is obtained by chemical modification and is distinguishable from the degraded galactomannan of present claim 12. See also present claim 31, which further emphasizes this distinction.

De La Torre discloses a partially hydrolyzed guar gum (PHGG). However, the molecular weight and viscosity thereof are not taught by De La Torre. Thus, even if the cited references were to hypothetically be combined with each other, they still cannot achieve the present invention.

Nevertheless, the Examiner notes at page 3 of the Office Action that

“It would have been *prima facie* obvious to a person of ordinary skill in the art at the time of the claimed invention to use partially hydrolyzed guar gum disclosed by De La Torre in the method disclosed by Bijlsma, because partially hydrolyzed guar gum in the absence of further chemical modification was known to be useful for treating IBD as disclosed by De La Torre, i.e., the results obtained by such substitution would have been expected.”

Applicants respectfully disagree with the Examiner’s reasoning.

The slightly negatively charged non-digestible polysaccharides of Bijlsma reduce the uptake of high molecular weight substances, allergens and microorganisms through the intestinal wall. In particular, Bijlsma relates to reduction of the free transport of such substances through the tight junctions of the intestines, without the transport of low molecular weight substances. That is, the method of Bijlsma discloses that transport via the tight junctions of the intestines is effectively reduced by further chemical modification, while polysaccharides without chemical modification have no effect (see Fig. 2 of Bijlsma). This clearly teaches away from a combination of the PHGG of De La Torre without any chemical modification. In other words, a skilled artisan would not combine Bijlsma with De La Torre. And, even if combined, there would be no expectation of success since Bijlsma teaches inferior results occur with polysaccharides without chemical modification. Further, even if combined, each of the cited references fails to teach or suggest using a specific degraded galactomannan having a molecular weight of 8,000-50,000 in an amount sufficient to lower the activity of myeloperoxidase and TNF- α .

Also, Applicants acknowledges that Bijlsma actually describes at page 6, line 6 that the compositions can be used for inflammatory bowel disease (IBD). However, there is no experimental data for supporting this disclosure. Bijlsma merely discloses that polysaccharides modified with further chemical processing can reduce transport via the tight junction of the intestines. In this context, Fig. 2 of Bijlsma illustrates that the composition without any modification is not effective and thus, teaches away from the present invention.

Further, as explained in the previous Reply of November 2, 2010, the test data in Test Examples 2-1 to 2-4 of the specification prove superior results with respect to the present

invention. For instance, a review of the results of Tables 6, 8, 10 and 12 reveals that the liquid foods of Examples 2-1 to 2-4 exhibit excellent effects for patients with ulcerative colitis, Crohn's disease, and bowel Behçet disease. In contrast, the liquid foods of Comparative Examples 2-1, 2-4, 2-6 and 2-8 are found to show only slight efficacy for patients with ulcerative colitis, Crohn's disease, and bowel Behçet disease, and the liquid foods of Comparative Examples 2-2, 2-5, 2-7, and 2-9 are not found to show any efficacy for any one of the patients.

However, the Examiner asserts at page 4 of the Office Action that

The test data has been considered but has not been found persuasive since the effectiveness of guar for the treatment of IBD would have been expected from the combination of teachings by Bijlsma and De La Torre. The additional effect of lowering activity of MPO and TNF- α with administration of guar gum would have been inherent in the methods disclosed by Bijlsma and De La Torre.

The Examiner's rationale is misplaced. Whether or not results are unexpected must be evaluated in the context of Bijlsma as compared to the claimed invention. If the Examiner were free to combine references and conclude that results are inherent in the combination, it would be impossible to ever argue secondary considerations. Simply put, this would amount to comparing the present invention with the present invention. The Examiner must consider the results of the specification and cannot argue that such results are inherent in a combination of Bijlsma and De La Torre.

Reconsideration and withdrawal of the obviousness rejection are accordingly requested.

Conclusion

In view of the above remarks, Applicants believe the pending application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie, Registration No. 42874, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

APR 13 2011

Dated: _____

Respectfully submitted,

By _____



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Attachments: 1. PTO SB08 form filed on November 2, 2010.

2. A full copy of Japanese References Nos. JP 2002-531510; JP 2003-534777; and JP 11-507406 and English Abstracts thereof.